

Amendments to the Claims

The following is a listing of all the claims submitted in this application including the present status of each. Any claims canceled or withdrawn in this application are done so without prejudice or disclaimer of any subject matter. Applicants reserve the right to pursue any canceled claims in continuing or divisional applications. By the present paper, claims 1-2, 5-6, 9, 11-16 and 18 have been amended, claims 7-8 have been canceled and new claim 19 has been added.

Listing of Claims.

1 (currently amended). A method of optimizing cardiac resynchronization therapy provided to a patient with ventricular dysynchrony including ~~the step of~~

- (a) non-invasively measuring hemodynamic and pulmonary performance in terms of data representing selected variables indicative of one or more a function functions selected from the group consisting of forward pump function (stroke volume output), or retrograde effects on filling pressures, pulmonary venous flow, and gas exchange at the alveolar/capillary membrane interface or a combination thereof during exercise; and
- (b) utilizing said data as representing dependent variables to adjust selected pacing parameters including atrial-ventricular (AV) delay and left ventricular-right

ventricular (VV) delay.

2(original). A method as in claim 1 wherein said forward pump function of the heart is derived from a parameter selected from the group consisting of the oxygen pulse (VO₂/HR) and carbon dioxide pulse (CO₂/HR) or a combination thereof.

3(original). A method as in claim 1 wherein said retrograde effect on filling pressures, pulmonary venous flow, and gas exchange at the alveolar/capillary membrane interface is derived from the ventilatory equivalent for CO₂ (VE/VCO₂) .

4(original). A method as in claim 2 wherein said retrograde effect on filling pressures, pulmonary venous flow, and gas exchange at the alveolar/capillary membrane interface is derived from the ventilatory equivalent for CO₂ (VE/VCO₂) .

5(currently amended). A method as in claim 1 including ~~the step of utilizing additional cardiopulmonary exercise variables selected from the group consisting of end tidal CO₂ (ETCO₂) and the ventilatory efficiency slope (linear slope of VE/VCO₂ ventilation timing induces (VT/Ti, VT/RR, Ti/Te and VT/VE).~~

6(currently amended). A method as in claim 4 including ~~the step of utilizing additional cardiopulmonary variables selected from the group consisting of end tidal CO₂ (ETCO₂) and the ventilatory efficiency slope (linear slope of VE/VCO₂) ventilation timing induces (VT/Ti, VT/RR, Ti/Te and VT/VE).~~

7-8(canceled).

9(currently amended). A method as in claim 6 including ~~the~~

~~step of acquiring, collecting and displaying said non-invasive cardiopulmonary exercise variables during low intensity exercise and storing them said variables as data sets, each set being associated with a unique value of atrial-ventricular (AV) delay and right left ventricular-left right ventricular (VV) delay.~~

10(original). A method as in claim 9 wherein the values for AV and VV delay are defined in a boundary conditions table unique to a pacemaker manufacturer of interest.

11(currently amended). A method as in claim 9 including ~~the step of utilizing the stored cardiopulmonary variable data sets to assist a physician in selecting the optimal combination of AV and VV delay values from several possible such values as defined in a boundary condition table unique to a pacemaker manufacturer of interest uniquely for individual patients.~~

12(currently amended). A method as in claim 8 9 wherein including selection of the an optimal combination of AV and VV delay values includes using the following steps:

- (a) ~~executing an AV/VV Delay Optimization Protocol Execute delay optimization protocol defining a time schedule for System Operator Tasks and Data Processing Tasks system operator tasks and data processing tasks for each unique value of AV and VV delay as defined in a boundary condition table unique to a pacemaker manufacturer of interest;~~
- (b) storing variable values measured for each breath during

the ~~Delay Optimization Protocol~~ delay optimization protocol into a Stored Data Sets table for subsequent analysis;

- (c) computing and storing a central tendency and percent deviation from the central tendency for each measured variable in each data set obtained immediately after collection ~~in step 9(b)~~ into an Intermediate table for subsequent analysis;
- (d) computing and storing into a Decision Matrix ranking, values for quantifying the response to changes in AV and VV delay settings using the values obtained in ~~step 9(c)~~;
- (e) computing and storing into a Decision Matrix deviation indices to provide a qualitative assessment of the variability of the data sets used to compute the ranking values obtained in ~~step 9(d)~~;
- (f) computing and storing into a Decision Matrix separation indices to provide a qualitative assessment of the magnitude of the difference between the central tendencies of the data sets used to calculate the ranking values in ~~step 9(d)~~;
- (g) printing a report of the Decision Matrix with all values used to compute average rank, deviation, and separation in ~~steps 9(d), 9(e), and 9(f)~~;
- (h) printing a graphical report in the form of a histogram having two juxtaposed bars - one bar representing the

ranking values determined in ~~step~~ (d), and another bar representing the average deviation % computed from ~~step~~ 9(e) - and the separation indices computed in 9(f); and (i) programming AV and VV delay values that provide the best forward pump function and the best retrograde effect on filling pressures, pulmonary venous flow, and gas exchange at an alveolar/capillary membrane interface using quantitative and qualitative data computed in ~~steps~~ (a) through (h).

13 (currently amended). A method as in claim 12 wherein the variables computed in ~~steps~~ (a) to (f) are represented in other common graphical formats selected from the group consisting of lines, bars, and pie charts.

14 (currently amended). A method as in claim 1 wherein the said data representing selected variables are measured under steady-state conditions and are treated as dependent variables for the purposes of ~~lead placement~~ and selection of the optimal combination of AV and VV delay values which are independent variables.

15 (currently amended). A method as in claim 1 wherein a common single set of equipment is utilized to optimize all phases/aspects of cardiac resynchronization therapy, including device implantation appropriate rate response during exercise/activity and device programming, including dynamic AV and VV delay of which resting AV and VV delay are a portion thereof.

16(currently amended). A method as in claim 11 wherein a ~~common single~~ set of equipment is utilized to optimize all phases of cardiac resynchronization therapy, including ~~device implantation appropriate rate response during exercise/activity and device programming, including dynamic AV and VV delay of which resting AV and VV delay are a portion thereof.~~

17(original). A method as in claim 11 wherein decisions can be made from quantitative and qualitative information.

18(currently amended). A method as in claim 1 including ~~the step of measuring retrograde effects using an end-tidal CO₂ analyzer analysis.~~

19(new). A method as in claim 1 including utilizing additional cardiopulmonary variables selected from the group consisting of end tidal CO₂ (ETCO₂), ventilatory equivalents (VE/VCO₂), and ventilation timing indices and sub-components (VT/Ti, VT/RR, TiTe and VT/VE).